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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,818	09/29/2003	Mark B. Knudson	14283.1USI2	6678

7590 04/26/2006

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/675,818	KNUDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/02/04, 01/23/04, 02/09/04, 04/12/04, 07/19/04, 08/06/04, 09/27/04, 05/27/05, 01/21/05, 08/31/05, 02/02/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method for electrically stimulating the enteric nervous system, classified in class 607, subclass 40.

II. Claims 11-14, drawn to a method for electrically stimulating and blocking activity of the vagus nerve, classified in class 607, subclass 48.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as within a method that does not require stimulation of the vagus nerve, but instead includes stimulation of any other nerve of the enteric nervous system, the greater splanchnic nerve being but one example. Subcombination I also has separate utility such as within a method that does not apply any blocking signal(s) to the nerve being stimulated. See MPEP § 806.05(d).

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Timothy R. Conrad on April 19, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims

11-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on January 2, 2004, January 23, 2004, February 9, 2004, April 12, 2004, July 19, 2004, August 6, 2004, September 27, 2004, January 21, 2005, May 27, 2005, August 31, 2005 and February 2, 2006 have been acknowledged and are being considered by the Examiner.

Specification

7. The disclosure is objected to because of the following informalities: the "Cross-Reference to Related Applications" section should be updated with the appropriate serial number and current status of each related application. Appropriate correction is required.

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the claims are directed to nerve stimulation and nerve blocking techniques to electrically stimulate discharge of secretions of pancreo-biliary organs to enhance digestion of food through the alimentary tract. The claims are not directed to stimulating and/or blocking the nerves that innervate the pacemaker region of the stomach or to stimulating and/or blocking nerves of the enteric nervous

system to treat irregular GI tract motility rhythms. The following title is suggested: *Nerve Stimulation and Blocking for Treatment of Gastrointestinal Disorders.*

Claim Objections

9. Claim 4 is objected to because of the following informalities: there appears to be a typographical error in the fourth line of the claim. The Examiner suggests changing "electrode and create a stimulation signal in said vagus nerve" to "electrode in order to create a stimulation signal in said vagus nerve" to provide clarification. Appropriate correction is required.

10. Claim 5 is objected to because of the following informalities: there appears to be typographical errors in the second and fourth lines of the claim. At the second line, the Examiner suggests changing "on said vagus intermediate" to read "on said vagus nerve intermediate" to provide clarification that the proximal nerve conduction block is indeed applied to the vagus *nerve*. At the fourth line, the Examiner suggests changing "said nerve block selected" to read "said proximal nerve conduction block selected" to provide antecedent basis. Appropriate correction is required.

11. Claim 9 is objected to because of the following informalities: there appears to be a typographical error in the second line of the claim. The Examiner suggests changing "said electrical conduction block" to read "said electrical proximal nerve conduction block" to provide antecedent basis. Appropriate correction is required.

12. Claim 10 is objected to because of the following informalities: there appears to be typographical errors in the claim. At the second line, the Examiner suggests changing "on said vagus with" to read "on said vagus nerve with" to provide clarification that the distal nerve conduction block is indeed applied to the vagus *nerve*. At the third and fourth lines, the

Examiner suggests changing "said proximal and distal nerve blocks" to read "said proximal and distal nerve conduction blocks" to provide antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 2-3 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 2 recites the limitation "said alimentary tract" in line 2 and line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 3 recites the limitation "said alimentary tract" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

17. As to Claim 10, it is unclear as to which direction distal nerve conduction block is selected to block passage of the stimulation signal.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Terry, Jr. et al. (U.S. 5,540,730) (herein Terry, Jr.). As to Claim 1, Terry Jr. discloses a method and apparatus for treating patients with at least one of a plurality of gastrointestinal disorders (such as hypomotility or hypermotility) (see Terry, Jr. Abstract). It is inherent that motility disorders of the gastrointestinal tract are characterized at least in part by abnormal gastrointestinal system activity attributed at least in part to altered autonomic balance (see Terry Jr. column 3, lines 1-6). The method of Terry Jr. comprises selectively and electrically stimulating the vagus nerve, which is part of the enteric nervous system of a patient, to enhance a functional tone of the enteric nervous system (i.e. stimulate neural impulses and produce excitatory neurotransmitter release by the vagus nerve to treat a motility disorder) (see Terry Jr. Abstract, column 1, lines 10-35 and column 2, lines 28-40). Terry Jr. further discloses that the stimulation is applied with a frequency of occurrence selected to elevate nerve activity sufficient to relieve symptoms of the motility disorder of interest (see Terry Jr. Fig. 5, column 7, lines 62-67, column 8, lines 1-5 and column 9, lines 15-44).

20. As to Claim 4, Terry Jr. further discloses that the electrical stimulation is created by placing an electrode set 25 on a vagus nerve 28 of the patient and applying an electrical stimulating current to the electrode set 25 in order to create a stimulation signal in the vagus nerve 28 (see Terry Jr. Figs. 3-4 and column 7, lines 30-36).

21. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchal et al. (U.S. 6,853,862) (herein Marchal). As to Claim 1, Marchal discloses a method for treating at least one of a plurality of gastrointestinal disorders of a patient (such as a wide variety of pancreatic diseases). It is inherent that pancreatic disorders of the gastrointestinal tract are

characterized at least in part by abnormal gastrointestinal system activity attributed at least in part to altered autonomic balance (see Marchal column 1, lines 8-36 and lines 60-63, column 3, lines 13-33). The method of Marchal comprises electrically stimulating the nerves innervating the pancreas 30 of a patient (i.e. the vagus nerve 41) to influence pancreatic secretions. All nerves that innervate the pancreas 30, including the vagus nerve 41, are part of the enteric nervous system and it is inherent that the electrical stimulation of Marchal enhances functional tone of the enteric nervous system (see Marchal column 3, lines 34-63). Marchal further discloses that the stimulation is applied at a frequency of occurrence selected to elevate nerve activity sufficient to relieve symptoms (see Marchal column 5, lines 12-50).

22. As to Claim 2, Marchal discloses that the method includes electrically stimulating 97 pancreo-biliary organs via stimulating a desired organ or nerve of the GI tract (see Marchal column 5, lines 1-10) to stimulate discharge or endocrine and/or exocrine secretions of the pancreo-biliary organs into a duodenum 28 of the patient by an amount sufficient to enhance transport of contents through a gastrointestinal organ of the alimentary tract (see Marchal Figs. 6a-b, 7a-b, 8a-8b and columns 5-6).

23. As to Claim 3, Marchal discloses that the method includes electrically stimulating pancreo-biliary organs via stimulating a desired organ or nerve of the GI tract (see Marchal column 5, lines 1-10) to stimulate discharge or endocrine and/or exocrine secretions of the pancreo-biliary organs into a duodenum 28 of the patient by an amount sufficient for receptors in a GI organ of the patient to respond to the secretions to contribute to an enhancement of functional tone (i.e. better GI tract motility) of the enteric nervous system (see Marchal Figs. 6a-b, 7a-b, 8a-8b and columns 5-6).

24. As to Claim 4, Marchal discloses that the electrical stimulation may be created by placing electrodes 50 on a vagus nerve 41 of the patient and applying an electrical stimulation current to the electrode in order to create a stimulation signal in the vagus nerve 41 (see Marchal Fig. 2, column 4, lines 65-67 and columns 5-6)

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry Jr. in view of Cohen et al. (U.S. 6,684,105) (herein Cohen). As to Claim 5, Terry Jr. discloses the claimed invention as discussed above except that it is not specified that the method includes applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system.

Cohen, however, discloses a method and apparatus for treating a condition of a patient (such as a gastrointestinal motility disorder) where an electrode device 18 is adapted to be coupled to a longitudinal nervous tissue (such as the vagus nerve) 40 and a control unit 50 is adapted to drive the electrode device 18 to apply to the nervous tissue 40 a current which is capable of inducing action potentials that propagate in the nervous tissue in a first direction (stimulation towards an organ of interest such as the stomach or any portion of the GI tract) 20,

and suppress action potentials from propagating in the nervous tissue 40 in a second direction, opposite the first direction (blocking signal towards the central nervous system) 40 (see Cohen Fig. 1 and Abstract). The method and apparatus of Cohen is used to provide for treatment of motility disorders, while minimizing undesired side effects caused by stimulation of the nerves controlling the digestive system and is capable of being used with the method and apparatus of Terry, Jr. (see Cohen column 4, lines 36-41 and lines 58-67, column 5, lines 1-19 and column 9, lines 1-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Terry, Jr. in view of Cohen to include the steps of applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system in order to minimize undesired side effects caused by stimulation of the nerves controlling the digestive system.

27. As to Claim 8, Cohen discloses that the proximal nerve conduction block is an electrical conduction block (i.e. an electric field) (see Cohen column 7, lines 54-65).

28. As to Claim 9, Cohen discloses that the electrical proximal nerve conduction block (towards the CNS 30) is selected to function during periods of application of the electrical stimulation current (towards the organ of interest 20) (see Cohen column 6, lines 65-67).

29. As to Claims 6-7, the previously modified Terry Jr. reference discloses the claimed invention as discussed above except that the nerve conduction block is not a cryogenic block or a pharmacologic block. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Terry Jr. in view of Cohen with either

a cryogenic block or a pharmacologic block, because Applicant has not disclosed that a cryogenic block or a pharmacologic block provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrical conduction block as taught by Cohen, because it provides proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system in order to minimize undesired side effects caused by stimulation of the nerves controlling the digestive system and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Terry Jr. in view of Cohen.

Therefore, it would have been an obvious matter of design choice to modify Terry Jr. in view of Cohen to obtain the invention as specified in the claim(s).

30. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terry Jr. in view of Cohen as applied to claims 1 and 4-5 above, and further in view of Gross et al. (U.S. 2003/0045909) (herein Gross). The previously modified Terry Jr. reference discloses the claimed invention as discussed above except that it is not specified that the method further comprises applying a distal nerve conduction block on the vagus nerve with the site of the electrical stimulation disposed between the proximal and distal nerve conduction blocks.

Gross, however, disclose a method and apparatus for selective nerve fiber stimulation where a stimulation cathode is located in-between a proximal blocking anode and a distal blocking anode (see Gross Abstract and Figs. 2A and 4). The Examiner considers the method and apparatus of Gross to be analogous to that of Terry Jr. and Cohen since they are all methods or stimulating a nerve to treat a condition of a patient. It would have been obvious to one having

ordinary skill in the art to modify the method of Terry, Jr. in view of Cohen and in further view of Gross to include applying a distal nerve conduction block on the vagus nerve with the site of the electrical stimulation disposed between the proximal and distal nerve conduction blocks to allow for selective nerve fiber stimulation.

31. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal in view of Cohen. As to Claim 5, Marchal discloses the claimed invention as discussed above except that it is not specified that the method includes applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system.

Cohen, however, discloses a method and apparatus for treating a condition of a patient (such as a gastrointestinal motility disorder) where an electrode device 18 is adapted to be coupled to a longitudinal nervous tissue (such as the vagus nerve) 40 and a control unit 50 is adapted to drive the electrode device 18 to apply to the nervous tissue 40 a current which is capable of inducing action potentials that propagate in the nervous tissue in a first direction (stimulation towards an organ of interest such as the stomach or any portion of the GI tract) 20, and suppress action potentials from propagating in the nervous tissue 40 in a second direction, opposite the first direction (blocking signal towards the central nervous system) 40 (see Cohen Fig. 1 and Abstract). The method and apparatus of Cohen is used to provide for treatment of gastrointestinal disorders, while minimizing undesired side effects caused by stimulation of the nerves controlling the digestive system (see Cohen column 4, lines 36-41 and lines 58-67, column 5, lines 1-19 and column 9, lines 1-17). Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the method of Marchal in view of Cohen to include the steps of applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system in order to minimize undesired side effects caused by stimulation of the nerves controlling the digestive system.

32. As to Claim 8, Cohen discloses that the proximal nerve conduction block is an electrical conduction block (i.e. an electric field) (see Cohen column 7, lines 54-65).

33. As to Claim 9, Cohen discloses that the electrical proximal nerve conduction block (towards the CNS 30) is selected to function during periods of application of the electrical stimulation current (towards the organ of interest 20) (see Cohen column 6, lines 65-67).

34. As to Claims 6-7, the previously modified Marchal reference discloses the claimed invention as discussed above except that the nerve conduction block is not a cryogenic block or a pharmacologic block. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Marchal in view of Cohen with either a cryogenic block or a pharmacologic block, because Applicant has not disclosed that a cryogenic block or a pharmacologic block provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrical conduction block as taught by Cohen, because it provides proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system in order to minimize undesired side effects caused by stimulation of the nerves controlling the digestive system and since it appears to be an

arbitrary design consideration which fails to patentably distinguish over Marchal in view of Cohen.

Therefore, it would have been an obvious matter of design choice to modify Marchal in view of Cohen to obtain the invention as specified in the claim(s).

35. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal in view of Cohen as applied to claims 1 and 4-5 above, and further in view of Gross. The previously modified Marchal reference discloses the claimed invention as discussed above except that it is not specified that the method further comprises applying a distal nerve conduction block on the vagus nerve with the site of the electrical stimulation disposed between the proximal and distal nerve conduction blocks.

Gross, however, disclose a method and apparatus for selective nerve fiber stimulation where a stimulation cathode is located in-between a proximal blocking anode and a distal blocking anode (see Gross Abstract and Figs. 2A and 4). The Examiner considers the method and apparatus of Gross to be analogous to that of Marchal. and Cohen since they are all methods or stimulating a nerve to treat a condition of a patient. It would have been obvious to one having ordinary skill in the art to modify the method of Marchal in view of Cohen and in further view of Gross to include applying a distal nerve conduction block on the vagus nerve with the site of the electrical stimulation disposed between the proximal and distal nerve conduction blocks to allow for selective nerve fiber stimulation.

Double Patenting

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37. Claims 1 and 4-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/674,324. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

38. Claims 1 and 4-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/756,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

39. Claims 1 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 13-17, 19 and 24-28 of copending Application No. 11/192,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

40. Claims 5-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 13-17, 19 and 24-28 of copending Application No. 11/192,750 in view of Cohen. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious

broadening of the scope of the patented claims or an obvious variant thereof. In addition, 1-5, 13-17, 19 and 24-28 of copending Application No. 11/192,750 discloses synonymous limitations as the claims in the current application except that it is not specified that the method includes applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system.

Cohen, however, discloses a method and apparatus for treating a condition of a patient (such as a gastrointestinal motility disorder) where an electrode device 18 is adapted to be coupled to a longitudinal nervous tissue (such as the vagus nerve) 40 and a control unit 50 is adapted to drive the electrode device 18 to apply to the nervous tissue 40 a current which is capable of inducing action potentials that propagate in the nervous tissue in a first direction (stimulation towards an organ of interest such as the stomach or any portion of the GI tract) 20, and suppress action potentials from propagating in the nervous tissue 40 in a second direction, opposite the first direction (blocking signal towards the central nervous system) 40 (see Cohen Fig. 1 and Abstract). The method and apparatus of Cohen is used to provide for treatment of gastrointestinal disorders, while minimizing undesired side effects caused by stimulation of the nerves controlling the digestive system (see Cohen column 4, lines 36-41 and lines 58-67, column 5, lines 1-19 and column 9, lines 1-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method defined by the claims of Application No. 11/192,750 in view of Cohen to include the steps of applying a proximal nerve conduction block on the vagus nerve intermediate a site of the electrical

stimulation and a central nervous system of the patient with the proximal nerve conduction block selected to block passage of the stimulation signal to the central nervous system in order to minimize undesired side effects caused by stimulation of the nerves controlling the digestive system.

This is a provisional obviousness-type double patenting rejection.

Conclusion

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 04/21/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766